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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,603	04/16/2001	Satoru Todo	067242/0148	2083
22428	7590	02/24/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			KWON, BRIAN YONG S	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/807,603

**Applicant(s)**

TODO, SATORU

**Examiner**

Brian S Kwon

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2003 and 04 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 48,101,104 and 106-111 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48,101,104 and 106-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Summary of Action***

- I. The rejection of claims 101 and 104 under 35 USC 102(b) will not be maintained in light of the amendment/remarks.
- II. The rejection of claims 48, 101 and 104 under 35 USC 103(a) will be maintained for the reason of the record.
- III. Applicant's amendment necessitated a new ground of rejection in this Office Action.

### ***Status of Application***

1. By Amendment filed November 04, 2003, Claims 101 and 104 have been amended and Claims 106-111 have been amended. Claims 48, 101, 104 and 106-111 are currently pending for prosecution on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1614

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 48, 101, 104 and 106-111 are rejected under 35 U.S.C. 103(a) as obvious over Sonnino et al. (Digestive Diseases and Sciences, Vol. 42, No.5, May 1997) in view of Khau et al. (US 5986106).

Sonnino discloses PX-13 as a sPLA2 inhibitor, and it further states that PLA2 released during ischemia is a type-II substance, that sPLA2 contributes to ischemic reflow, and that control of sPLA2 activity protects tissue fragments from ischemia and reflow in cold preservation graft study (abstract and page 973, column 1, para. 2). More specifically, Sonnino teaches or suggests the use of sPLA2 inhibitors for intestinal ischemic-reperfusion injury (page 980, column 1, lines 1-13).

Khau teaches the use of the claimed compounds represented by the formula (I), namely CC(Cc1c[nH]c2ccccc12)COC(=O)O and its sodium salt, as sPLA2 inhibitor (column 12, line 52; Example 1) .

The teaching of Sonnino differs from the claimed invention in the use of the specific sPLA2 inhibitor represented by the formula (I) for the treatment or prevention of ischemia reperfusion injury, more specifically heart, liver, pancreas or kidney. To incorporate such teaching into the teaching of the Sonnino, would have been obvious in view of Khau teaches the use of CC(Cc1c[nH]c2ccccc12)COC(=O)O and its sodium salt as sPLA2 inhibitor.

One having ordinary skill in the art would have known that sPLA2 contributes to ischemia-reperfusion injury and inhibition of sPLA2 would be useful in treating or preventing ischemia-reperfusion injury. One having ordinary skill in the art would have expected that any

Art Unit: 1614

compounds that inhibit the secretion of sPLA2 would have similar therapeutic utility in the treatment or prevention of ischemia-reperfusion injury occurred in intestine as well as various other organs including liver, heart, kidney or pancreas. Furthermore, one having ordinary skill in the art would have been motivated to administer well known sPLA2 (as taught by Khau), with the reasonable expectation of success, to treat or prevent ischemia-reperfusion injury in occurred in intestine, heart, liver, pancreas or kidney. One having ordinary skill in the art would have motivated to make such modification to extend the usage of the claimed sPLA2 inhibitor, namely [[3-(2-amino-1,2-dioxoethyl)-2-ethyl-1-(phenylmethyl)-1H-indole-4-yl]oxy]acetic acid, in the treatment or prevention of ischemia-reperfusion injury occurred in intestine, heart, liver, pancreas or kidney.

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 48, 101 and 104 are properly rejected under 35 U.S.C. 103.

### ***Response to Arguments***

3. Applicant's arguments filed September 25, 2003 and November 04, 2003 have been fully considered but they are not persuasive.

Applicant's argument takes position that the effective filing date of the present invention is earlier than Khau' 106 and the Kau'106 cannot be qualified as 35 USC 102(b) reference. This argument is persuasive. Therefore, the rejection of claims 101 and 104 under 35 USC 102(b) is withdrawn.

Art Unit: 1614

Applicant's argument takes position that since Khau et al. is not prior art to the present application, the rejection of claims 48, 101 and 104 is not proper. The examiner disagrees. The effective filing date of Khau'106 is June 26, 1998 earlier than the effective filing date of the instant application, which is October 7, 1999, and is qualified as prior art of reference under 35 USC 103(a). Therefore, examiner maintains the original rejection.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

Application/Control Number: 09/807,603

Page 6

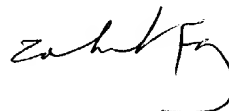
Art Unit: 1614

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY**  
**PRIMARY EXAMINER**  
**GROUP 1600**

A handwritten signature in black ink, appearing to read 'Zohreh Fay', written in a cursive style.